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Injunctive Relief: A Charming Betsy Boomerang

Harold C. Wegner



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INJUNCTIVE RELIEF:

A CHARMING BETSY BOOMERANG*

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I. INTRODUCTION

A successful patentee is often thought of as one who commercializes an invention on his own. Yet, the patent system also recognizes the achievements of an inventor who does not "work" his invention, i.e., enter it in the commercial market. Under *Continental Paper Bag*, the non-working patentee who successfully pursues a patent infringement suit is normally awarded injunctive relief to halt further infringement. But *should* a patentee who does not work his invention be entitled to such injunctive relief? Or should the infringer be permitted to continue practicing the invention by payment of a royalty (also referred to as a compulsory license)?

Challengers of *Continental Paper Bag* assert that compulsory licensing should be an available alternative to injunctive relief in infringement actions. This solution has been proposed both legislatively² and judicially.³ This article looks macroscopically at the position of U.S. industry in the global marketplace and analyzes the ramifications of

In determining equity [for injunctive relief], the court shall consider the fairness of the remedy in light of all the facts and the relevant interests of the parties associated with the invention. Unless the injunction is entered pursuant to a nonappealable judgment of infringement, a court shall stay the injunction pending an appeal upon an affirmative showing that the stay would not result in irreparable harm to the owner of the patent and that the balance of hardships from the stay does not favor the owner of the patent.

H.R. 2795, 109th Cong. § 7 (2005).

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The views expressed herein are entirely the author's, are pro bono and do not necessarily reflect the views of any organization or client of that organization.

^{**}Former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School; Partner, Foley & Lardner LLP. [hwegner@foley.com]

¹ Cont'l Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405 (1908).

² If enacted, legislation introduced by Lamar Smith, (TX-21), would add the following paragraph to 35 U.S.C. § 283 (2006):

³ The *eBay* case poses petitioner's question: "Whether the Federal Circuit erred in setting forth a general rule in patent cases that a district court must, absent exceptional circumstances, issue a permanent injunction after a finding of infringement." Petition for Writ of Certiorari, eBay, Inc. v. MercExchange, LLC, 401 F.3d 1323 (Fed. Cir. 2005), *cert. granted*, 163 L.Ed.2d 567 (U.S. Nov. 28, 2005) (No. 05-130). While granting *certiorari* on this question, *sua sponte*, the Court added a *second* question to be considered on appeal: "Whether this Court should reconsider its precedents, including *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908), on when it is appropriate to grant an injunction against a patent infringer." *eBay*, 163 L.Ed.2d 567 (U.S. Nov. 28, 2005) (No. 05-130).

departing from the *Continental Paper Bag* precedent, taking into account the context of U.S. treaty commitments and American patent policy toward foreign patent regimes.

This article begins with an explanation of the basic concept of a patent "working" requirement.⁴ There was a sentiment, reflected in early international patent agreements, which favored a working requirement in some countries, particularly nineteenth century Germany.⁵ The United States opposed this movement; the first Supreme Court challenge after domestic implementation of the Paris Convention squarely rejected the European initiative.⁶

The United States, led by the pharmaceutical industry, created a treaty framework to restrict a foreign government's grant of compulsory licenses as part of an increased emphasis on global patent protection.⁷ The procedure took a full decade.⁸ Several propatentee reforms were subsequently introduced as part of minimum standards for each country, including limitations on compulsory licenses.⁹ One of the key restrictions is that a "working" license may not even be *applied* for until three years have passed *after* the grant of a patent.¹⁰ Additionally, the grounds for a compulsory license application other than non-working are very limited.¹¹

Historically, Americans opposed to interpretations of treaties that compromise domestic law have simply ignored the relevant treaty provisions. This is no longer possible. It is now well settled law under the modern interpretation of *Charming Betsy*¹² that when a domestic statute can be interpreted in either a manner consistent with or inconsistent with the intentions evidenced by a treaty, the consistent interpretation governs.¹³ If an American attempted to ignore provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), the mandatory dispute settlement panel resolution under the Marrakesh Agreement Establishing the World Trade Organization ("WTO") would apply.¹⁴ Thus, if matters are not resolved domestically, any other TRIPS member state could bring the United States to a dispute settlement panel in Geneva, creating a TRIPS boomerang.¹⁵

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⁴ See infra Part II, Rejection of a European "Working" Concept.

⁵ See discussion infra Part II.A. European Evolution of a "Working" Requirement.

⁶ See discussion infra Part II.B, Continental Paper Bag Repudiation of German "Working."

⁷ See discussion infra Part III, TRIPs Limitations on Compulsory Licenses.

⁸ See discussion infra Part III.A, The Decade-Long Evolution of TRIPS: 1984 to 1994.

⁹ See discussion infra Part IV.B, The Right to a "Working" License.

¹⁰ See discussion infra Part IV.C, Paris Proscriptions on Compulsory Licenses.

¹¹ See discussion infra Part IV.D, Grounds for a Compulsory License Beyond Non-Working.

¹² Murray v. The Schooner Charming Betsy, 6 U.S. (2 Cranch) 64 (1804).

¹³ See discussion infra Part IV, The Charming Betsy Impact on American Law.

Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 (1994) [hereinafter TRIPS]. appendix 1C to the Agreement Amending the General Agreement on Tariffs and Trade [hereinafter GATT] and Creating the World Trade Organization [hereinafter WTO]. *See* General Agreement on Tariffs and Trade, Oct. 30, 1997, 67 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

¹⁵ Harold C. Wegner, *TRIPs Boomerang—Obligations for Domestic Reform*, 29 VAND. J. TRANSNAT'L. L. 535, 558 (1996); *see also infra* Part VI, Resolution Here—or via the WTO in Geneva.

II. REJECTION OF A EUROPEAN "WORKING" CONCEPT

A. European Evolution of a "Working" Requirement

Until the past decade, most of the advocates for a "non-working" compulsory license have been foreign. The debate over a right to "work" an invention when the patentee refrains from putting the invention to commercial use has persisted for roughly 150 years. The U. S. involvement in the European debates over working requirements goes back to the Vienna Congress of 1873, which predates the Paris Convention by ten full years. At the time of Vienna, the German Reich was emerging in the era of Bismarck and Germany was debating the introduction of its own federal patent system. There was a great deal of doubt about the exclusivity of the patent right, likely influenced by Austrian compulsory licensing law. Triggering American concern "was the compulsory working requirement, under which a patented article had to be manufactured

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¹⁶ In the context of the Paris Convention, the meaning of the term "working" must be determined from the official French term *exploiter*. However, at the Rome Conference of 1886 it was determined that "each country may determine for itself the meaning of the term 'exploiter." STEPHEN P. LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS, § 323, 524 n.32 (1975) (citations omitted). "Working" is not defined in *Black's Law Dictionary* (8th ed. 2004), but under a definition for "monopoly" there is the following quotation from William Blackstone: "[T]he statute of monopolies, 21 Jac. I. c. 3, allows a royal patent of privilege to be granted for fourteen years to any inventor of a new manufacture, for the sole *working* or making of the same; by virtue whereof a temporary property becomes vested in the patentee." 2 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND 407 (1766) (emphasis added). The same statutory provision is cited in *Pennock v. Dialogue*, 27 U.S. (27 Pet.) 1, 20 (1829) (Story, J.) (quoting The Statute of Monopolies, 21 Jac. ch. 3 (1623)). *See also* United States v. Line Material Co., 333 U.S. 287, 339 (1948) (Burton, J., dissenting) (quoting United States v. Dubilier Condenser Corp., 289 U.S. 178, 186, 187 (1933)); Markman v. Westview Instruments, Inc., 52 F.3d 967, 1011 (Fed. Cir. 1995) (en banc) (Newman, J., dissenting), *aff'd* 517 U.S. 370 (1996) (quoting the same

English statutory provision).

17 See supra note 8 and accompanying text. See also Radio Corp. of Am. v. Radio Eng'g Labs, Inc.,
293 U.S. 1, 4 n.2 (1934) ("Whenever there are interfering patents, any person interested in any one of them, or in the working of the invention claimed under either of them, may have relief against the interfering patentee . . .") (quoting R.S. § 4918 (35 U.S.C. § 66) (emphasis added); Topliff v. Topliff, 122 U.S. 121, 129 (1887) ("We paid royalty from the fact that we supposed that we were working under his original patent . . . Butterworth v. U.S. ex rel. Hoe, 112 U.S. 50, 62 (1884) (citing the "provisions of section 4918, Rev. St. [where it is] enacted that in case a patent is actually, though erroneously, issued, interfering with another, any person interested in any one of them, or in the working of the invention . . . may have relief against the interfering patentee") (emphasis added); Pickering v. McCullough, 104 U.S. 310, 319 (1881) ("It is objected, however, that the machines described in these patents are mere paper machines, not capable of successful practical working.") (emphasis added).

Some usage suggests any use of an invention qualifies as working. *See* Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 418 (1912) (quoting an 1873 English patent to Deighton for "improvements in the arrangement and mode of *working* an apparatus for the manufacture of Bessemer steel") (emphasis added); Lovell Mfg. Co. v. Cary, 147 U.S. 623, 634 (1893) ("[I]t does not amount to invention to discover that an old process is better in its results, when applied to a new *working*, than would have been expected; the difference between its prior *working* and the new *working* being only one of degree, and not one of kind.") (emphasis added); Root v. Third Ave. R. Co., 146 U.S. 210, 225 (1892) ("It cannot be fairly said from the proofs that the plaintiff was engaged in good faith, from the time the road was put into operation, in testing the *working* of the structure he afterwards patented.") (emphasis added); McClain v. Ortmayer, 141 U.S. 419, 425 (1891) (The "patentee has claimed more than is necessary to the successful *working* of his device.").

¹⁸ Edith Tilton Penrose, *The Development of the International Convention for the Protection of Intellectual Property, Chapter III* (1951), *in* THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM 635, 637 (Frederick Abbott et al. eds., 1999).

in Austria within a year from the issue of the patent." Forty years before the Vienna meeting, the United States had a brief four year experiment with a working requirement against foreign inventors: from 1832 to 1836 a working requirement was imposed on foreign inventors, and *only* foreign inventors.²⁰

Against U.S. opposition, a working requirement was approved as a local national right at the Vienna Congress (where the majority of delegates were German). A resolution "recommended compulsory licensing of patents 'in cases in which the public interest should require it."²¹ The debates leading up to the Paris Convention focused on a need for working under the view of certain Continental countries. This led to the inclusion of working as part of the German patent law, introduced in 1877.²²

In the year following the introduction of the German law, the venue for further international debates shifted to Paris, where three-fifths of the nearly 500 delegates to the Paris Conference of 1878 were French.²³ A resolution was approved there stating that "[p]atents ought to assure, during their entire duration, to inventors or their assigns, the exclusive right to the exploitation of the invention and not a mere right to a royalty paid to them by third parties."²⁴

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The only qualification [to the exclusive right of the patent] ever made was against aliens, in the act of 1832. That act extended the privilege of the patent law to aliens, but required them "to introduce into public use in the United States the invention or improvement within one year from the issuing thereof," and indulged no intermission of the public use for any period longer than six months. A violation of the law rendered the patent void. The act was repealed in 1836.

Cont'l Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 429 (1908). Other cases have mentioned this as well:

Congress, in the choice of means of promoting the useful arts by patent grants, could have provided that the grant should be conditioned upon the use of the patented invention, as in fact it did provide by the Act of 1832 (4 Stat. 577) authorizing the issue of patents to aliens conditioned upon the use of the invention, which provision was later repealed (5 Stat. 117, 125). But Congress was aware that an unpatented invention could be suppressed and the public thus deprived of all knowledge or benefit of it. It could have concluded that the useful arts would be best promoted by compliance with the conditions of the statutes which it did enact, which require that patents be granted only for a limited term upon an application fully disclosing the invention and the manner of making and using it. It thus gave to the inventor limited opportunity to gather material rewards for his invention and secured to the public the benefits of full knowledge of the invention and the right to use it upon the expiration of the patent.

Special Equip. Co. v. Coe, 324 U.S. 370, 378 (1945).

²⁰ As stated in *Continental Paper Bag*:

²¹ See Penrose, supra note 17, at 637-38.

²² "The origin of [compulsory licensing under Paris Convention] article 5A(2) can be traced to 1873, when the parties to the Vienna Congress resolved that compulsory licenses should be made available if warranted by 'public interest.'" Srividhya Ragavan, The Jekyll and Hyde Story of International Trade: The Supreme Court in PhrRMA v. Walsh and the TRIPS Agreement, 38 U. RICH. L. REV. 777, 787 n.61 (2004). See also Michael Halewood, Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law, 35 OSGOODE HALL L.J. 243, 266 (1997). The Vienna Congress culminated in the Paris Convention in 1883. Id. Although the Vienna Congress produced no binding legal instrument, in 1877, the provision was adopted into the German law. Id. Article 5A(2) of the Paris Convention details that "failure to work the patent could not result in forfeiture unless compulsory licensing was an inefficient remedy. Therefore, compulsory licensing replaced forfeiture as the favored remedy to deter abuse by the patentee." Patrick Marc, Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?, 21 N.Y.L. SCH. J. INT'L & COMP. L. 109, 112 (2001).

See Penrose, supra note 17, at 638.
 Id. at 641.

The original penalty for non-working was far more severe than a compulsory license: the patent could be forfeited.²⁵ In preparation for the Paris Convention of 1883, a Draft Convention of 1880 codifying the existing local European working laws was put forth. The Draft specified that "the patentee shall be subject to the obligations to work his [invention] in conformity with the law of the country into which he introduces patented articles."²⁶ The original Paris Convention thereby avoided the controversy by solely maintaining forfeiture provisions rather than explicitly providing for compulsory licensing.²⁷ As a compromise, compulsory licenses were reserved for individual countries as a discretionary matter of local law to prevent abuses.²⁸

The Paris Convention version in effect at the time of *Continental Paper Bag* was the 1900 Brussels Revision, which was identical to the original Convention insofar as working requirements were concerned. There was continued debate over the working requirement at the time of the 1900 Brussels Revision, but no agreement could be reached for changing the treaty provisions.²⁹ A slight modification was made in the 1911 Washington Revision that stipulated "[a] patent may not be forfeited for non-working . . . until after a period of three years from the date of filing the application . . . and only in the case the patentee cannot justify his inaction."³⁰

It was not until the 1925 Hague Revision that a compulsory license was substituted for forfeiture for the non-working of an invention.³¹ The 1925 Hague Revision abolished forfeiture as a penalty for nonworking but introduced the following provision:

[E]ach country shall have the right to take the necessary legislative measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work. . . . [T]he patent may not be subjected to such measures before the expiration of at least three years from the date of grant or if the patentee proves the existence of legitimate excuses.³²

As defined in the current version of the Paris Convention, "abuses. . . from the exercise of the exclusive [patent] rights" include a "failure to work."³³ This definition traces back to the deliberations at the time of the Hague Revision:

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²⁵ There was widespread support for a strong working requirement. However, the matter was not by any means unanimous. In addition to American opposition to working, the delegations of Great Britain, Russia and Turkey urged abolition of the working requirement at the 1880 conference. *See* LADAS, *supra* note 16, § 320, 519 n.17.

²⁶ *Id.* (quoting the draft of Art. 5 of the *Conférence de Paris* (1880), p. 56).

²⁷ Id.

²⁸ [Compulsory licensing] was introduced . . . as a means to restrict the extreme remedy of patent forfeiture in the cases of failure to work or other "abuses which might result from the exclusive rights conferred by the patent." Countries were not allowed to impose forfeiture unless they had first attempted to remedy the "abuse" through the grant of a compulsory license.

Paul Champ & Amir Attaran, *Patent Rights and Local Working under The WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 371-72 (2002) (footnotes omitted).

²⁹ LADAS, *supra* note 16, at 519.

³⁰ *Id*.

³¹ *Id.* at 520.

³² *Id.* at 526-27.

³³ The Paris Convention for the Protection of Industrial Property, July 14, 1967, Art. 5A(2), 21 U.S.T. 1583. ("Each country of the Union shall have the right to take legislative measures providing for the grant

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In the discussion of article 5 in the Plenary Committee [of the 1925 Hague Revision], the Canadian delegation proposed that it be made clear that failure to work the invention is such an abuse of the exercise of the patentee's exclusive rights. To satisfy this desire, the last words of the second paragraph of article 5 were inserted, "for example, failure of working."³⁴

B. Continental Paper Bag Repudiation of German "Working"

¶13 In 1908, five years after the Paris Convention was domestically implemented, Continental Paper Bag became the first Supreme Court case to seriously consider foreign patent law in the context of compulsory licensing. The 1900 Brussels Revision was the first version to be officially ratified in the U.S. The original 1883 Paris Convention was only "proclaimed" by the President (which itself took place only in 1887).³⁵ There had been increased awareness of the Paris Convention through participation in the treaty negotiations commencing in Brussels in 1897. These negotiations precipitated the eventual domestic implementation of the Paris Convention; leading to the creation of a Congressional Commission in 1898 and the enactment of related legislation in 1902 that became effective in 1903.³⁶

Due to the international debates concerning the Brussels Revision, the Continental Paper Bag Court was aware that various European countries included a "working" requirement in their patent laws. The Court expressly recognized the divergence of foreign law: "In some foreign countries the right granted to an inventor is affected by nonuse. This policy, we must assume, Congress has not been ignorant of nor of its

of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."). See Srividhya Ragavan, supra note 22, at 787 n.61 (citing Michael Halewood, *supra* note 21 at 266) ("A compulsory licensing provision was first incorporated into the Paris Convention in 1925 at the Revision Conference at The Hague."); Article 5 of the Hague Revision permitted compulsory licensing of patents not worked locally. Id. at 266-67; see also Patrick Marc, supra note 22, at 112.

[T]he Convention for the Protection of Industrial Property, and the final protocol thereto, between several states and nations, concluded at Paris, March 20, 1883, [was] subsequently acceded to by the United States, and proclaimed by the President thereof, June 11, 1887.... The uniform construction of that convention by the Patent Office officials, and by the courts of this country, has been that the convention is not self-executing, but requires the aid of an act of Congress

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The Paris Convention was not . . . self-executing and required implementing legislation. The bill eventually enacted by Congress had been drafted by a commission created by Act of Congress in 1898 to study the effect of the Paris Convention on United States law. The commission submitted a report, dated November 27, 1900 and printed in 1902, entitled Report of the Commissioners Appointed to Revise the Statutes Relating to Patents, Trade and Other Marks, and Trade and Commercial Names, Senate Document No. 20, 56th Congress, 2d Session.

Kawai v. Metlesics, 480 F.2d 880, 884 (C.C.P.A. 1973).

³⁴ LADAS, *supra* note 16, at 527-28.

³⁵ Rousseau v. Brown, 21 App. D.C. 73, 76 (D.C. Cir. 1903) (Alvey, C.J.):

Id. 36 Renewed interest in the Paris Convention commenced in 1897 when the first session of the Brussels Revision conference took place. Hennebique Const. Co. v. Myers, 172 F. 869, 880 (3d Cir. 1909) (Archbald, J., concurring). This led to creation of a Congressional commission in 1898 to study domestic implementing legislation which was finally enacted in 1902:

effects."³⁷ However, the Court pointed out that Congress "has, nevertheless, selected another policy [rather than a working requirement]; it has continued that policy through many years. We may assume that experience has demonstrated its wisdom and beneficial effect upon the arts and sciences."³⁸ The general rule of injunctive relief set forth in *Continental Paper Bag* has now been followed for nearly a full century.

To be sure, lower courts have used equity powers to deny injunctive relief in exceptional circumstances, particularly where the grant of an injunction would have had negative effects on the health of the populace.³⁹ The Federal Circuit has acknowledged a line of case law as being applicable in "rare instances . . . to deny injunctive relief in order to protect the public interest."⁴⁰ Much has been written about the limited exceptions to injunctive relief through compulsory licensing.⁴¹

III. TRIPS LIMITATIONS ON COMPULSORY LICENSES

A. The Decade-Long Evolution of TRIPS: 1984 to 1994

TRIPS grew out of the efforts of the movie and software industries. Both of these industries had an interest in strong copyright enforcement in foreign, particularly developing, nations. In 1984 the drug industry suffered a major defeat, losing trade secret-based exclusivity for pioneer drugs. At the same time, Pfizer, a leader in the industry, joined forces with film and software interests to create the Intellectual Property Committee. This convinced the United States Trade Representative to introduce TRIPS

³⁷ Cont'l Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 429 (1908).

³⁸ *Id.* at 429-30.

³⁹ Rite-Hite Corp. v. Kelley Co., 56 F.3d.1538, 1547-48 (Fed. Cir. 1995) (Lourie, J.) (en banc) ("If a patentee's failure to practice a patented invention frustrates an important public need for the invention, a court need not enjoin infringement of the patent."); *see also* Kearns v. Chrysler Corp., 32 F.3d 1541, 1551 (Fed. Cir. 1994) (Lourie, J.) (Injunctive relief "is not absolute . . . but is discretionary.").

⁴⁰ See, e.g., Hybritech, Inc. v. Abbott Lab., 849 F.2d 1446 (Fed. Cir. 1988) (public interest required that injunction not stop supply of medical test kits that the patentee itself was not marketing); Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 146 F.2d 941, 946 (9th Cir. 1945) (public interest warranted refusal of injunction on irradiation of oleomargarine); City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 593 (7th Cir. 1934) (injunction refused against city operation of sewage disposal plant because of public health danger).

⁴¹ City of Milwaukee, 69 F.2d at 593; Rebecca S. Eisenberg, Exclusive Rights And Experimental Use, 56 U. CHI. L. REV. 1017, 1077 n.230 (1989); Maureen A. O'Rourke, Toward A Doctrine of Fair Use in Patent Law, 100 COLUM. L. REV. 1177, 1209 n.130 (2000); Janice M. Mueller, Patent Misuse through the Capture of Industry Standards, 17 BERKELEY TECH. L.J. 623, 661 (2002) (citing Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 146 F.2d at 954-56); Mark A. Lemley & Ragesh K. Tangri, Ending Patent Law's Willfulness Game, 18 BERKELEY TECH. L.J. 1085, 1123 n.114 (2003) (citing Vitamin Technologists, 146 F.2d at 944-47).

⁴² Prior to 1984, a pioneer drug manufacturer could use data exclusivity provisions to extend its monopoly on a product long past the expiration of the patent. Due to data exclusivity, any other manufacturer would have to *duplicate* the work of a New Drug Application to create the generic "me too" product. In 1984, the Abbreviated New Drug Application was introduced under the *Drug Price Competition and Patent Term Restoration Act of 1984* (28 U.S.C. § 355 (2000)). This simplified procedure was intended to end almost all of the duplicative effort problems of the past. Pfizer was the key industry lobbyist involved in this legislation, and it was able to gain a special ten year data-based exclusivity for one of its major drugs.

⁴³ The establishment of this coalition is explained by Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World,* 3 Nw. J. TECH. & INTELL. PROP. 160, 171 (2005). The CEO's of Pfizer and IBM joined with the traditional copyright industry to create this

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as a key component of the Uruguay Round of the General Agreement on Tariffs and Trade ("GATT").⁴⁴ Ten years later at Marrakesh, a revised version of the treaty was signed. The treaty was reborn under the new name of the World Trade Organization ("WTO") with TRIPS as its very centerpiece.⁴⁵

TRIPS deals with intellectual property. However, the interests of the several industries were essentially separate. The movie and software industries initially focused on copyright issues, leaving the patent law provisions almost entirely to the pioneer pharmaceutical manufacturers. Thus, the American pioneer pharmaceutical industry—enthusiastically joined by colleagues from Europe and Japan—drew up the tightest possible rules *against* compulsory licensing that could be imagined at the time. The several industries and industries initially focused on copyright issues, leaving the patent law provisions almost entirely to the pioneer pharmaceutical industry—enthusiastically joined by colleagues from Europe and Japan—drew up the tightest possible rules *against* compulsory licensing that could be imagined at the time.

When TRIPS was signed in 1994, the nascent software industry had no concern for patents. It was four years before the *State Street Bank* case⁴⁸ provided a huge green flag to patent software inventions. Nor were the major interests in the electronics industry initially concerned about patent law problems, as they could see the clear benefits of copyright protection for their products and were unaware of the problem of non-working patentees. It was only when the Foundation of the late Jerome Lemelson sought high royalty payments without working their patents that the modus operandi of the current non-working patentee-plaintiffs developed.

The negotiations over TRIPS were almost completely successful insofar as mandating strong measures to limit compulsory licensing of patented products. But, *no* change was made to the *domestic* law at the time of TRIPS insofar as compulsory licensing was concerned. It would have been an extremely simple matter to have included the entire TRIPS compulsory licensing proscriptions *directly* in American domestic patent law because there was no opposition to be seen at the time on *this* set of issues: The "fast track" mechanism made it certain that TRIPS provisions would pass as part of the domestic law, had they simply been proposed for the "fast track" package.⁴⁹

The reason that no change was made in the domestic law was because it was a *given* to the proponents of TRIPS that the standard was an international *codification* of the American law of injunctive relief. Few, if any, of the lobbyists supporting TRIPS had read the American statutory basis for exclusive rights and fewer still knew the

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alliance. Id. at 171 n.125.

⁴⁴ General Agreement on Tariffs and Trade, Oct. 30, 1997, 67 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

⁴⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 (1994), Appendix 1C to the Agreement Amending the General Agreement on Tariffs and Trade and Creating the World Trade Organization.

⁴⁶ The generic drug industry was still in the early stages of its development at this time, so there was no balancing of this industry's interests against those of the pioneer drug manufacturers.

⁴⁷ The complexity of the regulatory approval process has recently been evidenced in the real-life example of Merck's decade-long attempt to gain approval of a new type of chemotherapy. *See* Merck KGaA v. Integra Lifesciences I, Ltd., 125 S.Ct. 2372, 2377 (2005).

⁴⁸ State Street Bank & Trust v. Signature Fin. Group, 149 F.3d 1368 (Fed. Cir. 1998).

⁴⁹ Under "fast track," numerous provisions were included in the domestic implementing legislation which Congress could only vote up or down, *without any amendment*. It would have been a trifling matter to have included additional parts of TRIPS as part of the domestic law. *See* Patricia Isela Hansen, *The Impact of the WTO and NAFTA on U.S. Law*, 46 J. LEGAL EDUC. 569, 571 (1996) (citing Harold Hongju Koh, *The Fast Track and United States Trade Policy*, 18 BROOK. J. INT'L L. 143 (1992)) (noting "critici[sm] of the 'fast-track' procedures used to approve [TRIPS]. For example, fast-track provisions limiting floor debate and prohibiting amendment have been termed 'undemocratic.'").

significance of the *Continental Paper Bag* case as the cornerstone for the interpretation of the American law.

B. The Right to a "Working" License

A loophole that opens the door to compulsory licenses exists where the patentee refrains from practice of the invention, i.e., he does not "work" the invention. This may be deemed to constitute "an abuse of intellectual property rights" within the meaning of TRIPS. TRIPS Whether a patentee refusing to license or "work" his patented invention is a basis for a compulsory license may be considered an open question under TRIPS section 8, *Control of Anti-Competitive Practices in Contractual Licenses*. The opening section states that TRIPS countries "agree that some . . . conditions . . . which restrain competition may have adverse effects on trade and may impede the . . . dissemination of technology. Consequently, "[n]othing in [TRIPS] shall prevent Member [States] from specifying in their legislation . . . conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. The otherwise conditions precedent for grant of a compulsory license of an unsuccessful negotiation and the limitation of a compulsory license to a domestic market are inapplicable.

C. Paris Proscriptions on Compulsory Licenses

Even if TRIPS, *itself*, leaves the door open to a compulsory license as an "abuse," TRIPS incorporates by reference substantive provisions of the Paris Convention which contain proscriptions against any grant of a non-working license. The Paris Convention, first, proscribes an *application* for a compulsory license for non-working until the

⁵⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999); 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

Nothing in this Agreement shall prevent Member [States] from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member [State] may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

TRIPS art. 40(2).

⁵¹ "Member [States] agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology." TRIPS art. 40(1).

⁵² TRIPS art. 40(2).

⁵³ TRIPS art. 31(b).

⁵⁴ TRIPS art. 31(f).

⁵⁵ Member [States] are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur...
TRIPS art. 31(k).

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expiration of three years from the *grant* of the patent.⁵⁶ But, even after the expiration of this period, if the patentee provides "legitimate reasons" for non-working, then the compulsory license shall be refused.⁵⁷

Under the Paris Convention, and hence TRIPS, compulsory licenses were reserved for individual countries as a discretionary matter of local law to prevent "abuses . . . from the exercise of the exclusive [patent] rights." A "failure to work" is the only concrete example of such an abuse that is given. ⁵⁹

[Compulsory licensing] was introduced . . . as a means to restrict the extreme remedy of patent forfeiture in the cases of failure to work or other 'abuses which might result from the exclusive rights conferred by the patent.' Countries were not allowed to impose forfeiture unless they had first attempted to remedy the 'abuse' through the grant of a compulsory license.⁶⁰

Thus, in the first instance, a compulsory license is only possible if the conditions of the Paris Convention are met. The principal condition under the Paris Convention is that there is a very long time lag between the filing of a patent application and the time when a compulsory license can be *sought*. It often takes three or more years for a patent to be granted. Then, the compulsory license still cannot be sought until three further years after the grant. So, if, a patent is granted only five years after filing, the compulsory license under the Paris Convention can only be applied for eight years after filing.

The theory behind the three year deferral of a compulsory license is to give the patentee time to "work" the invention himself. Yet, he can also work the invention simply by granting licenses to others who in turn work the invention and supply the marketplace. To the extent that the United States were to either judicially or legislatively introduce a compulsory license scheme for non-working of an invention where the patentee seeks to license an entire industry, then the patentee will obviously give a preferential rate to a first or second licensee who will endeavor to work the invention. Then, with the prophylactic of an *existing* working of the invention on behalf of the patentee, the non-working license is then closed.

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⁵⁶ Or, if the patent is granted in less than one year (which rarely occurs), then the period expires four years from the application date. Both provisions are covered under the Paris Convention art. 5A(4): A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last. . . . *Id*

⁵⁷ "[The compulsory license] shall be refused if the patentee justifies his inaction by legitimate reasons." *Id.*

⁵⁸ Paris Convention for the Protection of Intellectual Property, art. 5A(2), *revised* July 14, 1967, 21 U.S.T. 1583 Stockholm Revision (1967). "A compulsory licensing provision was first incorporated into the Paris Convention in 1925 at the Revision Conference at The Hague." Ragavan, *supra* note 22 at 787 n. 61. Article 5 of the Hague Revision permitted compulsory licensing of patents not worked locally. Halewood, *supra* note 22, at 266-67; *see also* Marc, *supra* note 22, at 112.

⁵⁹ Paris Convention, art. 5A(2) ("Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.")

⁶⁰ Champ & Attaran, *supra* note 28.

D. Grounds for a Compulsory License Beyond Non-Working

Beyond non-working grounds, other compulsory licenses may be granted where the same three year rule of the Paris Convention is met and there is a case-by-case determination of the basis for a compulsory license. Here, the complex mechanism of TRIPS art. 31 must be followed: cumbersome procedural requirements that have no direct relevance to a non-working situation. First, there can be no blanket authorization for a TRIPS compulsory license as the "authorization of such use shall be considered on its individual merits." Second, and unlike the case of a non-working compulsory license, the compulsory license "use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." Furthermore, a compulsory license whose grant is not based upon the abuse of non-working cannot be used to supply the international market.⁶³

IV. THE CHARMING BETSY IMPACT ON AMERICAN LAW

In creating TRIPS, Americans in both industry and government delegations only considered the *export* of American standards to other countries. TRIPS was designed to create a complex set of minimum standards that would compel foreign governments to meet American standards of intellectual property protection. Yet, whatever standards are set in stone by treaty must be adhered to by the United States as well. Thus, TRIPS can operate as a boomerang to United States policy initiatives for countries seeking to retreat from these mandatory standards.⁶⁴

Neither TRIPS nor the Paris Convention are self-executing. Therefore both instruments are only a part of domestic law to the extent that there has been domestic implementing legislation. This point is stressed by the "52 Professors" ⁶⁵ who argue that because TRIPS is not a self-executing treaty it is inferior to the 1952 codification for injunctive relief in 35 USC § 283. ⁶⁶ The relevant intellectual property treaties are *not*

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⁶¹ TRIPS art. 31(a). This provision also applies in the case of non-working license.

⁶² TRIPS art. 31(b). However,

[[]t]his requirement may be waived by a Member [State] in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly

TRIPS art. 31(b).

⁶³ "[A]ny such use shall be authorized predominantly for the supply of the domestic market of the Member [State] authorizing such use[.]" TRIPS art. 31(f).

⁶⁴ Wegner, supra note 15; cf. Donald P. Harris, Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States, 25 Nw. J. INT'L L. & Bus. 99 (2004).

⁶⁵ Brief Amici Curiae of 52 Intellectual Property Professors In Support Of Petitioners, eBay, Inc. v. MercExchange, L.L.C., No. 05-130 (U.S. Jan. 26, 2006).

⁶⁶ *Id.* at 11-12. Analytically, it is difficult to consider *Continental Paper Bag* as *inconsistent* with the statute when for nearly fifty years *Continental Paper Bag* has been held to clearly represent the law in the wake of the 1952 codification. Since the TRIPS proscriptions on compulsory licensing were introduced as a cornerstone of that treaty and since there was a "fast track" legislative implementation process for the massive domestic law that *was* introduced, it can only be assumed that Congress considered there to be no

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self-executing and therefore are effective only to the extent that domestic law is consistent with such treaties. This is true both for the Paris Convention⁶⁷ as well as TRIPS.⁶⁸ Under *Charming Betsy*, however, domestic law should, to the extent possible, be construed consistent with treaties:

[A]n act of Congress ought never to be construed to violate the law of nations if any other possible construction remains, and, consequently can never be construed to violate neutral rights, or to affect neutral commerce, further than is warranted by the law of nations as understood in this country.⁶⁹

This is, of course, applicable to Paris and TRIPS.⁷⁰ Jackson points out that the "United States has a default position to interpret domestic statutes in accord with international law."⁷¹

As explained in *Hoffman-La Roche v. Empagran*, "this Court ordinarily construes ambiguous statutes to avoid unreasonable interference with the sovereign authority of other nations." This rule of construction reflects principles of customary international law, law that (we must assume) Congress ordinarily seeks to follow. ⁷³ *Charming Betsy* is

need for domestic implementing legislation for TRIPS arts. 30 and 31. Even if there is wiggle room from a naked reading of the statute to reach an interpretation inconsistent with *Continental Paper Bag*, the *Charming Betsy* canon of statutory construction compels a TRIPS-consistent result.

67 "It is well established that executory treaties (those treaties that are not self-executing) have no direct effect until implemented by domestic law." *In re* Rath, 402 F.3d 1207, 1209-10 (Fed. Cir. 2005). *See generally* 1 RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW: SUBSTANCE AND PROCEDURE § 6.6 (3d ed. 1999) (discussing executory and self-executing treaties). "Our predecessor court held that '[t]he Paris Convention was not . . . self-executing and required implementing legislation." Kawai v. Metlestics, 480 F.2d 880, 884 (C.C.P.A. 1973). We are bound by the decisions of the Court of Customs and Patent Appeals ('CCPA')." South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

⁶⁸ [TRIPs] (which incorporates the Paris Convention) [is] not self-executing as 19 U.S.C. § 3512(a)(1) specifically provides that '[n]o provision of any of the Uruguay Round Agreements [including TRIPs], nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.' Congress has also specifically precluded any person other than the United States from using TRIPs as a cause of action or a defense, and from challenging government action on the ground that such action is inconsistent with TRIPs.

Rath, 402 F.3d at 1210 n.2 (quoting U.S.C. § 3512 (2000)).

⁶⁹ Murray v. The Schooner Charming Betsy, 6 U.S. (2 Cranch) 64, 118 (1804).

⁷⁰ *Rath*, 402 F.3d at 1211 (citing *Charming Betsy*, 6 U.S. (2 Cranch) at 118); Allegheny Ludlum Corp. v. United States, 367 F.3d 1339, 1348 (Fed. Cir. 2004); Luigi Bormioli Corp. v. United States, 304 F.3d 1362, 1368 (Fed. Cir. 2002) ("In cases of ambiguity, we interpret a statute [to implement a treaty] as being consistent with international obligations.").

⁷¹ Vicki C. Jackson, Constitutional Comparisons: Convergence, Resistance, Engagement, 119 HARV. L. REV. 109, 113 n.17 (2005) (citing Charming Betsy, 6 U.S. (2 Cranch) at 118; The Paquete Habana, 175 U.S. 677, 700 (1900)).

U.S. 677, 700 (1900)).

⁷² 542 U.S. 155, 164 (2004); *see*, *e.g.*, McCulloch v. Sociedad Nacional de Marineros de Honduras, 372 U.S. 10, 20-22 (1963) (application of National Labor Relations Act to foreign-flag vessels); Romero v. Int'l Terminal Operating Co., 358 U.S. 354, 382-83 (1959) (application of Jones Act in maritime case); Lauritzen v. Larsen, 345 U.S. 571, 578 (1953) (same).

⁷³ See Hartford Fire Ins. Co. v. California, 509 U.S. 764, 817 (1993) (Scalia, J., dissenting) (identifying rule of construction as derived from the principle of "prescriptive comity"); Charming Betsy, 6 U.S. (2 Cranch) at 118 ("[A]n act of Congress ought never to be construed to violate the law of nations if any other possible construction remains"); RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES §§ 403(1), 403(2) (1986) (limiting the unreasonable exercise of prescriptive jurisdiction with

a necessary canon of statutory construction so that courts will not create conflicts with foreign laws and treaties. The *Charming Betsy* statutory construction rule "cautions courts to assume that legislators take account of the legitimate sovereign interests of other nations when they write American laws. It thereby helps the potentially conflicting laws of different nations work together in harmony – a harmony particularly needed in today's highly interdependent commercial world."⁷⁴

Justice Scalia has been perhaps the most adamant of any of the members of the Court in denying use of contemporary foreign law to interpret domestic statutory provisions. Yet, he clearly recognizes that foreign law is important where there is a question of how a treaty should be interpreted:

The object of treaties is to have nations agree on a particular course of action, and if I'm interpreting a provision of a treaty which has already been interpreted by several other signatories, I am inclined to follow the interpretation taken by those other signatories, so long as it's within the realm of reasonableness. I mean, if they've taken an absolutely unreasonable interpretation, of course I wouldn't follow it. But where it's within the bounds of the ambiguity of the bounds contained in the text, I think it's good practice to look to what other signatories have said, otherwise you're going to have a treaty that's interpreted different ways by different countries, and that's certainly not the object of the exercise. I also think that foreign law is sometimes relevant to the meaning of an American statute; for example, if the statute is designed to implement a treaty provision, the interpretation of that treaty provision by foreign courts is relevant to what the treaty means, and hence, relevant to what the American statute *implementing* the treaty means.⁷⁵

V. DEFINING THE CONTOURS OF TRIPS EXCLUSIVITY

At some point there is bound to be a test case as part of a mandatory dispute settlement panel whether compulsory licensing is a permitted remedy for the failure to locally "work" – or commercially "use" - an invention.

The American debates over exclusivity in Congress and in the courts may well yield a judicial or legislative result that waters down the exclusive rights under *Continental Paper Bag.* If this happens, then it will surely be argued in international fora *by the major countries* seeking to maintain drug exclusivity that the United States is in violation of TRIPS.

Conversely, developing countries will welcome any movement by the United States that gives a restrictive interpretation to TRIPS limitations on compulsory licenses; such countries will surely use any liberalization in American compulsory licensing provisions as basis for doing the same thing in the local laws around the world. Thus, if the United

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respect to a person or activity having connections with another State).

⁷⁴ F. Hoffman-La Roche, 542 U.S. at 164-65.

Justice Antonin Scalia, *International Law in American Courts*, Speech to the American Enterprise Institute, Washington, D.C. (February 22, 2006) http://www.joink.com/homes/users/ninoville/aei2-21-06.asp (last visited February 28, 2006) (original emphasis).

States government – whether by legislation or court decision – interprets TRIPS as permitting broad compulsory licensing of inventions, then an argument could be made that such an interpretation is satisfactory for *any* TRIPS country.

Ultimately, any major American liberalization of compulsory licensing will wind up before a WTO dispute settlement panel that will shape the contours of TRIPS insofar as defining the metes and bounds of what compulsory licensing practices are permitted under the treaty.

Proponents of eliminating the patent holder's exclusive right will surely turn to the 1925 Hague Revision of the Paris Convention which introduced a local right to grant compulsory licenses for abuses such as failing to work an invention. The Hague Revision "was significant because it gave recognition to failure to work as an 'abuse' of international law, for which compulsory licensing was the remedy of first resort." As noted by Champ & Attaran:

[F]ailure to work has been considered a prima facie 'abuse' of the patent privilege under international law. Indeed, until the early 1990s, almost every country in the world had local working requirements. . . . Interestingly, the Paris Convention only mentions compulsory licensing as a remedy for abuses, but is silent on compulsory licensing for public interest reasons.⁷⁷

Yet, to the extent that the electronics and software industries "win" by an acceptance of compulsory licensing on the basis of a failure of the patentee to work the invention, the pharmaceutical industry will be the big loser. A blueprint for developing country avoidance of patents will surely be painted if the Hague-based argument wins the day in Geneva.

The "52 Professors" argue that a TRIPS based argument belongs in the WTO mandatory dispute settlement arena and not before the Supreme Court. Indeed, were the Supreme Court to overrule *Continental Paper Bag*, then this is *precisely* where the matter will be headed. Here, a grand coalition of the 52 Professors, the electronics and software industries and all the developing countries of the world will be aligned against the pioneer drug manufacturers. Should such a coalition prevail at the WTO, then there will have been a dramatic reshuffling of the deck: an open invitation for every developing country to impose compulsory licensing thanks to such a precedent. Conversely, should the pioneer pharmaceutical industry prevail, the United States would be cast as the ultimate victim of a TRIPS boomerang.

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⁷⁶ Champ & Attaran, *supra* note 28, at 371-72; *see also* Ragavan, *supra* note 22, at 787 n.61 ("The [Paris] Convention seeks 'to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.") (quoting the Paris Convention, art. 5A(2)).

⁷⁷ Champ & Attaran, *supra* note 28, at 372-73.

⁷⁸ Brief Amici Curiae of 52 Intellectual Property Professors In Support Of Petitioners, *supra* note 65, at 11.

^{11.}There have already been several mandatory dispute settlement panels that have actively considered TRIPS intellectual property issues, some of which are cited in the brief *amicus curiae* of the Bar Association of the District of Columbia. Brief for Amici Curiae Bar Association of the District of Columbia, eBay, Inc. v. MercExchange, L.L.C., No. 05-130 (U.S. Jan. 26, 2006).

VI. RESOLUTION HERE - OR VIA THE WTO IN GENEVA

Until TRIPS, the intellectual property treaties were toothless and largely ignored by the patent community. But TRIPS, as part of the WTO and as successor to the GATT, took over and incorporated the mandatory dispute settlement procedures of the GATT. The previously unenforceable Paris Convention was suddenly given vitality because TRIPS incorporates by reference the key elements of the Paris Convention. The previously unenforceable Paris Convention of the Paris Convention.

Now, however, both the Paris Convention and TRIPS are mandatory for the United States insofar as there is a *mandatory* dispute settlement built into TRIPS for any violations of that treaty and also the major provisions of the Paris Convention.

To the extent that the United States maintains the philosophy of injunctive relief of *Continental Paper Bag*, there is a good chance that the strong proscriptions against compulsory licensing embedded in TRIPS will be sustained by the WTO. This will happen as the global case law evolves through dispute panel resolutions on a case by case basis. To the extent that there is any erosion of American domestic law inconsistent with a broad interpretation of TRIPS, then, surely, there will be a weakening of American patent rights abroad, particularly in developing countries. It is inconceivable that proponents of a strong right against compulsory licenses will be able to carry the day in Geneva if the number one proponent of such rights has eviscerated its own national law.

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⁸⁰ "The [dispute settlement] provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein." TRIPS art. 64(1). Dispute settlement was limited during the initial five year period after TRIPS came into force, which has now expired. TRIPS art. 64(2). "Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement." *Id*.

⁸¹ "In respect of Parts II [Standards concerning the availability, scope and use of Intellectual Property Rights], III [Enforcement of Intellectual Property Rights] and IV [Acquisition and maintenance of intellectual property rights and related *inter-partes* procedures] of this Agreement, Member [States] shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)." TRIPS art. 2(1).